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NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

Better Health
Through Responsible
Self-Medication

May 11, 1992

William E. Gilbertson, Pharm.D.
Director, Monograph Review Division
Office of OTC Drugs
Food and Drug Administration HFN-210
7520 Standish Place, Room 201
Rockville, MD 20855

Dear Dr. Gilbertson:

In preparation for our meeting on May 20, 1992 in relation to the safety and effectiveness of 2% hydroquinone as an OTC skin discoloration lightening agent, I enclose copies of the following materials which will be the basis for a portion of our presentation to FDA.

These materials include summary reports entitled: "Chronic Health Effects Testing for Hydroquinone" and "Salient Observations from the Published Literature on Exogenous Ochronosis Reportedly Associated with Skin Discoloration Fade Products." Four copies of each summary report are enclosed. Copies of references in relation to the former summary report are in preparation for FDA.

Sincerely yours,

R. William Soller, Ph.D.

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

Enclosures: "Chronic Health Effects Testing for Hydroquinone"

"Salient Observations from the Published Literature on Exogenous Ochronosis Reportedly Associated with Skin Discoloration Fade Products."

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